

SEP - 2 1999



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Lawrence T. Welch
Intellectual Property Services
Pharmacia & Upjohn
301 Henrietta St.
Kalamazoo, MI 49001

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,526,892

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,526,892, which claims the human drug product DOSTINEX® (cabergoline), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,276 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 1,276 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of August 4, 1998 (63 Fed. Reg. 41581). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,825) + 363 \\ &= 1,276 \text{ days}\end{aligned}$$

Since the regulatory review period began December 29, 1990, after the patent issue date (July 2, 1985), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the 14 year limitation of 35 U.S.C. § 156(c)(3) nor the limitations of 35 U.S.C. § 156(g)(6) operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	4,526,892
Granted	:	July 2, 1985

Original Expiration Date¹: July 2, 2002

Applicant: Patricia Salvati, et al.

Owner of Record: Upjohn & Pharmacia

Title: Dimethylaminoalkyl-(Ergoline8' β Carbonyl)-Ureas

Classification: 514/288

Product Trade Name: DOSTINEX® (cabergoline)

Term Extended: 1,276 days

Expiration Date of Extension: December 29, 2005

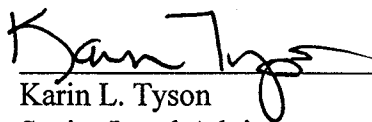
Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

By hand: Crystal Plaza Four, Suite 3C23
2201 South Clark Place
Arlington, VA 22202

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.


Karin L. Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: DOSTINEX® (cabergoline)
FDA Docket No.: 97E-0152

¹Subject to the provisions of 35 U.S.C. § 41(b).